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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,886

06/25/2003

Kieran P. Murphy

331202.00007

2271

27160 7590 07/09/2007
PATENT ADMINISTRATOR
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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,886

Applicant(s)

MURPHY ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/30/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Newly submitted claim 37 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 37 is directed to method claims which are patentably distinct from the device claims as originally presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

Applicant is suggested to request an interview (telephonic or personal) to clarify issues not understood by applicant in the future. The prosecution of this applicant has been delayed to applicant's request for clarification by paper and the processing of such paper.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of claims 31-36 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Applicant shows figure 7-8 as a kit which is very generic and shows no details with respect to intermediate portions, a figure 10 which is the spinal catheter and figure 9 which is a guidewire. With respect to claim 3, applicant has claimed features which appear such as specific portions of the catheter such as the intermediate portion and distal portion which applicant should refer to by reference number in the specification. Applicant has just broadly designated a needle or a catheter with a waist or a guidewire. If in fact these drawings are representative of what applicant is claiming then the drawing objections will be removed.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim limitations are directed to a combination of the elements (needle , guidewire, catheter, specific portions) with the functional language (configured for...) is not supported as originally filed in the disclosure/specification and by how it is currently claimed. The only support applicant has in the specification is in paragraph 25-26. There is a stylet which is withdrawn or removed from the Tuohy needle and not a guidewire. The guide wire is only disclosed as being removed from the catheter. The specification discloses a stylet is removed from the needle and the claims claim a guidewire is removed from the catheter. There appears to be new matter which is introduced in the present claims. Applicant is correct, the claims were not originally filed and not originally disclosed in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross (USPN 5,002,535).

Gross discloses a spinal catheter having a narrow end and outer surface forming a tapering continuously from the narrow end of the catheter to the seal. See figures 7-8 and column 8 , lines 33-49 and column 6, lines 17. Gross disclose the length of the catheter to be approximately 3.5 inches. See column 4, lines 10-12. It would be inherent that all the embodiments of the Gross as shown in figures 6-8 would be the same size.

Claims 18-19,23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Utterberg et al. (USPAP 2001/003149 A1).

Unterberg et al. discloses a catheter having a narrow end, an outer surface with a continuously taper. See figures 1-1a, 5-6. Utterberg et al. disclose a narrow end that is less than 14 Gauge (11-13 gauge) and the proximal end having a greater than 14 G (14-15 Gauge) and the taper being substantially along its entire length.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-21 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (USPN 5,002,535) or Utterberg et al. (USPAP 2001/003149 A1) in view of Karakelle et al. (USPN 5,061,254).

Gross or Utterberg et al. disclose the invention as substantially claimed. See Gross or Utterberg et al. above. Gross or Utterberg et al. both teach a needle structure/catheter to be inserted into a patient. However, Gross or Utterberg et al. is silent to an outer surface coating of infection resistant layer or adhesion resistant layer thereon. Karakelle et al. disclose a needle structure/catheter with a coating of anti-infective agents well known in the art to be inserted into a patient. Thus, it would have been obvious to one of ordinary skill in the art to modify needle/catheter structure of Gross or Utterberg et al. with a coating of anti-infective agents as taught by Karakelle et al. in order to avoid further introducing or exposing the patient with microbial or clotting.

Claims 25-30 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (USPN 5,002,535) in view of Utterberg et al. (USPAP 2001/003149 A1) and further in view of Karakelle et al. (USPN 5,061,254).

Gross discloses the invention as substantially claimed. See Gross above. Gross teaches a needle structure/catheter to be inserted into a patient having a continuous taper from the proximal to the distal end. However, Gross is silent to a 14 gauge size of the needle. Utterberg et al. teach a 14 gauge needle that tapers from the proximal end

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to the distal end. It would have been obvious to one of ordinary skill in the art to modify the gauge size as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended target size of the patient where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device would not be patentably distinct from the prior art.

With respect to claims 26-27, Gross in view of Utterberg et al. are silent to an outer surface coating of infection resistant layer or adhesion resistant layer thereon. Karakelle et al. disclose a needle structure/catheter with a coating of anti-infective agents well known in the art to be inserted into a patient. Thus, it would have been obvious to one of ordinary skill in the art to modify needle/catheter structure of Gross in view of Utterberg et al. with a coating of anti-infective agents as taught by Karakelle et al. in order to avoid further introducing or exposing the patient with microbial or clotting.

Response to Arguments

Applicant's arguments filed 06/30/06 have been fully considered but are not persuasive. Applicant appears to be arguing more narrow than claimed with respect to the term "rigid". Applicant has only claimed tubular structures which applicant has called "needle" and "catheter". One of ordinary skill in the medical art has used this terminologies broadly and interchangeably with 'cannula, catheter , needle , tubular or tube. Lacking any further structural distinguishing features, the Examiner is not convinced and is maintaining the rejection. Applicant is reminded that his claims are

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directed to a device claim. Applicant appears to be reading limitations in the dictionary into the terms. For the sake of argument, all tubular structure has some degree of flexibility or rigidity, thus a needle or cannula or catheter is a tubular structure which is flexible to some degree.

Claims 31-36 have been rejected as best understood by the Examiner and in the broadest interpretation.

This action is a second action non-final to respond to applicant's request for clarification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon-Fri (first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LoAn H. Thanh/

LoAn H. Thanh
Primary Examiner
Art Unit 3763

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